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**UNITED STATES DISTRICT COURT**

**CENTRAL DISTRICT OF CALIFORNIA**

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| Multiple Energy Technologies, LLC<br>Plaintiff,<br>v.<br>Hologenix, LLC,<br>Defendants. | Case No. 2:19-cv-01483-PA-RAO<br>**DECLARATION OF SETH CASDEN IN SUPPORT OF DEFENDANT'S OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION** |
| Hologenix, LLC<br>Counterclaimant,<br>v.<br>Multiple Energy Technologies, LLC<br>Counter-Defendant. | Complaint Filed: February 28, 2019 |

I, Seth Casden, declare as follows:

1. I am the CEO of Defendant Hologenix, LLC ("Hologenix"). The information contained herein is either personally known to me or has been obtained from (1) people whom I believe to be reliable and capable of ascertaining the facts described herein or (2) records maintained by Hologenix.

2. I submit this declaration in support of Defendants' Opposition to Plaintiff's Motion for a Preliminary Injunction.

3. I was one of the founders of Hologenix in 2002 and have been involved with Hologenix since then.

4. I have been CEO of Hologenix from 2005-2006 and again since November 2008, with the exception of the period from October 2017 through April 2019, when I served as President of Hologenix.

5. Hologenix currently has five full-time employees and three additional employees serving as full-time consultants.

6. Hologenix produces and markets Celliant, a patented technology comprised of a proprietary mix of naturally-occurring thermo-reactive materials that can be embedded into the core of a yarn or applied to a wide variety of fabrics. The resulting mineral matrix captures body heat and converts energy into Infrared (IR) energy, which is emitted back to the body where it can be absorbed by the tissues. This IR energy has been shown to cause a microdilation of the capillaries, increasing localized blood flow and improving oxygen uptake from the blood into the tissue to areas where Celliant products are worn or utilized near the body.

7. Hologenix has been developing Celliant (known as "Holofiber" until 2008) since its founding in 2002.

8. There is an extensive body of scientific evidence that establishes the benefits of IR emission, including its ability to increase blood flow and tissue oxygenation, and its effect on a number of health and wellness outcomes.

9. Over the course of 12 years since Celliant was developed, Celliant products have been evaluated in more than 1,000 individual Periflux 5000 TCPO2 tests (transcutaneous partial pressure of oxygen in millimeters of mercury per square inch) as well as a multitude of other tests and studies, including: ash analyses to confirm that Celliant has been appropriately incorporated into the company's finished products; dry rate testing demonstrating that Celliant products dry faster when exposed to body heat than standard polyester fabrics of the same weight and construction; insulation tests demonstrating Celliant fabrics' heat retention capability; IR absorption tests examining how much energy in the IR range is absorbed into Celliant fabric compared to non-Celliant fabric; IR emissivity tests examining the difference in IR emission between a Celliant fabric and a non-Celliant fabric; and Celliant-specific clinical studies that Hologenix sponsored as part of the development of the technology. This extensive body of evidence helps to demonstrate the benefits of IR emission, generally, and establishes those of Celliant, specifically. From 2003 to date, Hologenix has conducted nine clinical studies on Celliant including a total of five published papers. Additional clinical studies are planned for efficacy in both healthy and challenged population groups.

10. A table summarizing the nine completed Celliant clinical studies and two physical papers is publicly available on the Celliant website and attached to this Declaration as **Exhibit A**.

11. As the technology and its physiological effects became apparent to Hologenix, and were substantiated by clinical studies, Hologenix began to evaluate how the resulting Celliant products would be regulated by FDA.

12. Hologenix first proactively approached FDA in 2009 to determine the regulatory pathway and status of Celliant products regarding the Celliant technology. At that time, FDA informed Hologenix that a request for determination

could not relate to the technology alone, but rather needed to be tied to a product incorporating the technology.

13. Hologenix continued to engage repeatedly with FDA over the next two years and in March 2011, pursuant to feedback received from the agency, Hologenix presented a 513(g) submission to FDA. This submission sought feedback from the agency as to how FDA would classify certain athletic apparel that incorporated the Celliant material, and what regulatory framework the agency would apply to that apparel.

14. Subsequently, FDA indicated to Hologenix that because of the claims Hologenix had proposed in the 513(g) – including claims regarding increased local oxygenation, increased blood flow and circulation and increased tissue oxygen levels – Hologenix would need to obtain premarket review for the Celliant-containing products. After FDA confirmed this position on appeal during an August 2011 telephonic meeting, Hologenix considered whether FDA's "510(k)" pathway – in which a company asserts that its product is "substantially equivalent" to an already marketed predicate product – would be the appropriate pathway for premarket review of Celliant-containing products. There were however, no products on the market that could serve as appropriate predicates to support premarket review through the 510(k) pathway because Celliant products operated under a different mechanism of action than other IR products – such as IR saunas, lamps and therapy devices – that had already been authorized by FDA.

15. In October 2011, Hologenix filed a "pre-IDE" submission to FDA seeking additional guidance.

16. Based on the guidance FDA received based on its pre-IDE submission, in 2012, Hologenix decided to undertake a clinical study and submit a *de novo* request for Celliant, thereby seeing marketing authorization from FDA under an alternative pathway FDA has established for low-risk devices which lack a

legally marketed predicate and therefore cannot take advantage of the 510(k) process.

17. On March 17, 2014, Hologenix filed a *de novo* request for FDA review of Upper Torso Garments which incorporated Celliant, which sought to have the garments reclassified out of Class III and into "No Significant Risk" ("NSR") and Class II.

18. The Hologenix *de novo* request included a substantial body of scientific evidence – including nine Celliant clinical studies - demonstrating (a) the effects of IR technology, generally; (b) that Celliant exhibits IR effects; and (c) that IR products, including Celliant products, have desirable and helpful physiological effects on the human body. In July 2014, FDA sent Hologenix an eight-page letter with sixteen questions in which it indicated that, following the agency's initial scientific review of the *de novo* request, FDA had identified certain deficiencies in the application. The letter sought responses to a number of questions on a variety of issues, including specific questions about the clinical study data provided in the *de novo* submission. In particular, the letter posed a number of questions specifically related to Hologenix's pivotal Celliant clinical study.

19. Hologenix submitted a written response to FDA's deficiency letter on September 3, 2014.

20. On April 28, 2015, FDA sent Hologenix a six-page letter declining Hologenix's *de novo* request for classification of the Celliant garments into NSR and Class II. The letter stated that FDA continued to have questions and concerns about the scientific data and information evidence Hologenix had provided to the agency in support of its *de novo* request.

21. Based on Hologenix's review of FDA's denial letter, Hologenix believed that FDA had an incomplete and incorrect understanding of Celliant and the relevant scientific evidence. Thus, Hologenix continued to engage with FDA in order to educate the agency and to seek a different outcome.

22. Hologenix met twice with FDA in June 2015 to demonstrate to FDA Hologenix's efforts and to continue to address the agency's questions and concerns. A meeting on June 17, 2015 focused on the submission process and on the designation of claims as general wellness vs. medical. A second meeting on June 22, 2015 focused specifically on discussion of Hologenix's pivotal clinical study.

23. In advance of each meeting, Hologenix submitted proposed questions to FDA, and FDA responded with preliminary written responses. In one of its response letters, FDA identified certain specific issues and questions it wished to discuss with Hologenix regarding the clinical trial.

24. Hologenix's pre-meeting submission also sought FDA's written feedback as to the acceptable scope and types of statements that would be permitted for Celliant products, and included a list of proposed claims Hologenix sought to make. FDA's response identified certain of these claims as acceptable general wellness claims and indicated that other claims – including claims regarding injury, aches and pains, and muscle soreness - were medical indications that would require premarket review.

25. In August 2015, Hologenix engaged Experien Group LLC as medical device consultants to advise and assist Hologenix in its continued interaction with FDA.

26. Ultimately, after continued interaction between Hologenix, Experien Group and FDA to clarify the issues, FDA in 2016 determined that the *de novo* process was not, in fact, required for Celliant products provided they were intended for healthy individuals. Instead, following a subsequent pre-submission meeting request filed in February of 2016, and the agency's review of the data provided in the studies, in August of 2016 FDA presented Hologenix with a four-page regulatory options table that outlined several potential approaches for applications ranging from simple wellness claims through the filing of a new *de novo*. One option was the submission of a new 513(g) – that would permit the company's

proposed claims about local circulation and blood flow (which FDA had previously refused to permit) while allowing the Celliant products to be classified as medical devices.

27. Thus, on October 21, 2016, Hologenix submitted a new 513(g) request to FDA, which resulted in FDA's issuance on June 8, 2017 of the 513(g) determination letter determining that Celliant products are both medical devices and general wellness products. FDA advised Hologenix that it could use that phraseology to describe the result of the 513(g) consultation to the public. A copy of the 513(g) letter is attached to this declaration as **Exhibit B**.

28. While, at the time the initial 513(g) was filed in 2011, FDA told Hologenix that Celliant products required premarket review because of the intended marketing claims, by 2017 FDA decided not to require premarket review and to instead permit Hologenix to market Celliant products with claims about improved circulation and local blood flow and related health and wellness benefits, while exercising enforcement discretion and allowing the company to forgo premarket review and other regulatory requirements provided they were intended for healthy people.

29. Ultimately, the 513(g) determination letter was the result of nearly a decade of interaction with FDA, and approximately $500,000 in costs associated with the preparation and submission of various requests and other documents to that agency.

30. This decade-long interaction, over 2 years of which related to a *de novo* request, involved substantial review by, and discussion with, FDA of the scientific evidence Hologenix had developed in support of Celliant. In meetings and discussions with FDA throughout that decade-long period, the agency asked a multitude of detailed questions about the science on IR, generally, and Celliant, specifically, and did not simply offer a view on our proffered claims based on its

historical notions of the line between medical devices and general wellness products.

31. The path Hologenix followed with FDA is available to any owner or manufacturer of a product that produces IR, as is FDA's classification and the language it has advised can be used to describe our status.

32. I am aware of at least one other company using "FDA determined" language that is virtually identical to the language FDA's 513(g) letter to Hologenix indicated was permissible and using product claims that are quite similar to those Hologenix has made for Celliant. Specifically, Nanobionic, which markets its own IR technology for use in textiles, states the following on its website (www.nanobionic-group.com/#technology): "Products powered by Nanobionic Technology have been determined by the FDA to be medical devices as defined in section 201(h) of the Act and are also General wellness products. Products powered by Nanobionic Technology temporarily promote increased local blood flow at the site of application in healthy individuals. This increased blood flow can have a wide range of health benefits, including enhancing faster recovery, increasing strength and endurance, supporting heat generation, and increasing general wellness of being."

33. Throughout the years, Hologenix has sought to promote the Celliant technology to manufacturers of textiles, apparel, bedding and others through a wide variety of industry-specific marketing efforts, including meetings with numerous potential customers globally, appearing and presenting at multiple conferences, promotion of the product at over 30 trade shows over a period of more than 15 years, and many other avenues typically followed by companies working to promote a new technology and build a business. In the course of these efforts, we often encounter many competitors, but rarely, if ever, have we encountered Multiple Energy Technologies, LLC.

34. From 2009-2018, Hologenix was in varying stages of discussions with Under Armour with respect to supplying Celliant for Under Armour to use in some of its products.

35. These efforts led to Hologenix signing an agreement with Under Armour on February 23, 2018.

36. At the request of Under Armour, Hologenix was also in discussions with American Textile, Inc. in 2017 with respect to supplying American Textile with Celliant to use in some of its products, which it began supplying to American Textile in 2018.

37. Hologenix never had, and does not now have, a marketing plan that describes the technology as "FDA-approved" nor has it ever approved that language for a brand partner marketing products containing Celliant.

38. I am now aware that on fewer than ten occasions out of thousands of social media posts, employees of Hologenix or consultants authorized to post on our behalf erroneously referred to Celliant technology as "FDA-approved." Hologenix removed such references to this terminology as soon as it was brought to Hologenix' attention.

39. If Hologenix is required to communicate to its more than 100 global customers and their respective supply chains that it falsely advertised Celliant – or any of the other statements demanded by MET in its Application – this would irreparably damage Hologenix's reputation and its' relationships with those customers.

I declare that under penalty of perjury that the foregoing is true and correct.

DATED this 10 day of May, 2019.

Seth Casden